DMB

Display Date 8.31.97
Publication Date 9.4.97
Certifier C. Wilson

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0385]

Agency Information Collection Activities; Submission for OMB Review; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by (*insert date 30 days after date of publication in the* **Federal Register**).

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Margaret R. Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

Supplements to Premarket Approval Applications for Medical Devices

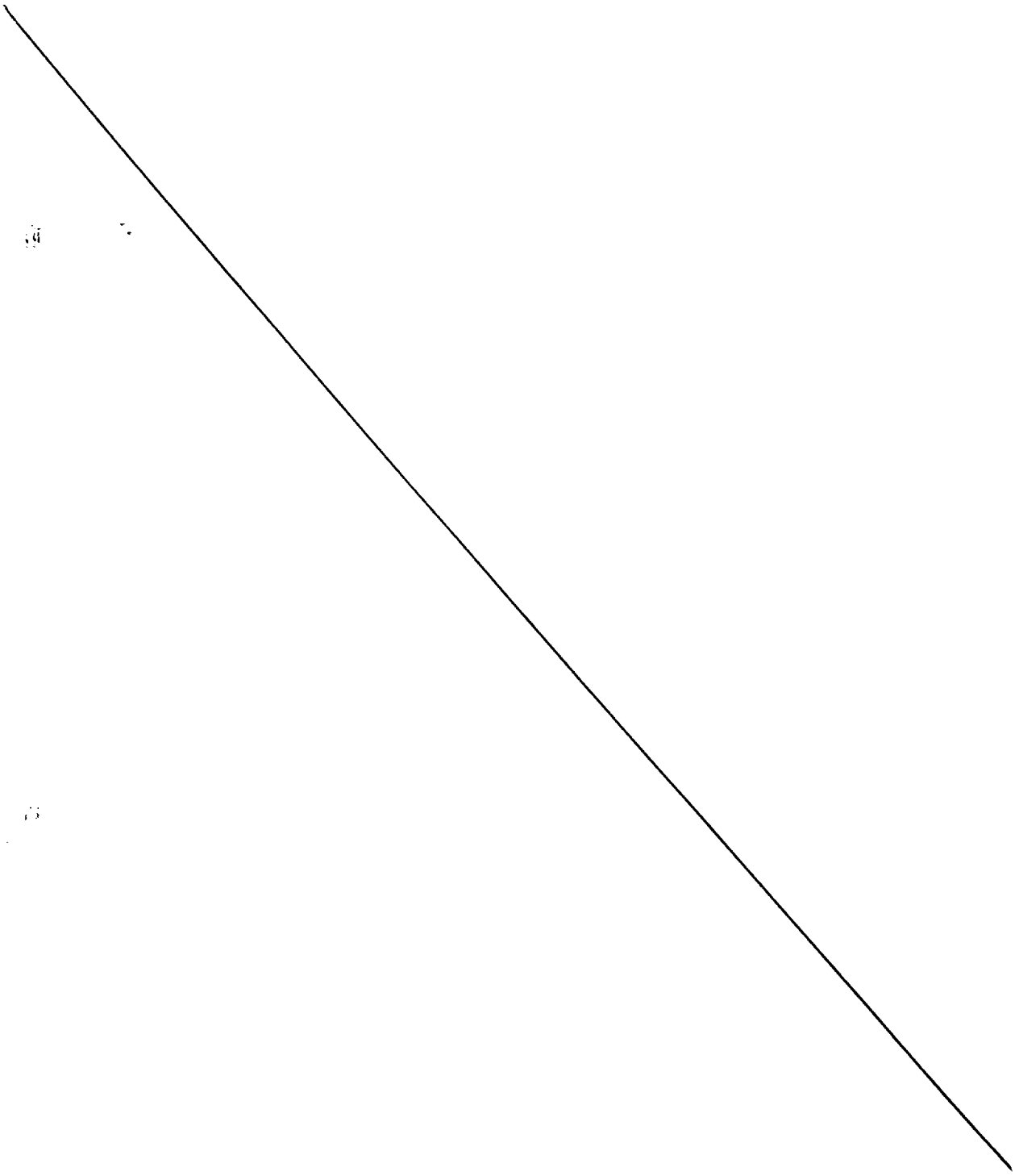
The Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105–115) added section 515(d)(6) to the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(6)), modifying FDA's statutory authority regarding premarket approval of medical devices. This new section provides for an alternate form of notice to the agency for certain types of changes to a device for which the manufacturer has an approved premarket approval application (PMA). Under section 515(d)(6) of the act, PMA supplements are required for all changes that affect safety and effectiveness, unless such changes involve modifications to manufacturing procedures or the method of manufacture. For those types of manufacturing changes, the manufacturer may submit to the agency an alternate form of notice in the form of a 30-day notice, or where FDA finds such notice inadequate, a 135-day PMA supplement. The 30-day notice must: (1) Describe the change the manufacturer intends to make, (2) summarize the data or information supporting the change, and (3) state that the change has been made in accordance with the requirements of 21 CFR part 820.

The manufacturer may distribute the device 30 days after FDA receives the notice, unless FDA notifies the applicant, within that 30-day period, that the notice is inadequate. If the notice is inadequate, FDA will inform the manufacturer that a 135-day supplement is required and will describe what additional information or action is necessary for FDA to approve the change. The rule would incorporate the provisions for a 30-day notice and 135-day supplements into FDA's regulations in § 814.39 (21 CFR 814.39) to reflect the changes made by FDAMA.

Description of Respondents: Businesses or other for profit organizations.

The information collection for § 814.39 has been approved by OMB until September 30, 1998, under Premarket Approval of Medical Devices (OMB control number 0910–0231) for a total of 36,063 hours. FDA believes that the submission of 30-day notices in lieu of PMA supplements will result in approximately a 10 percent reduction in the total number of hours needed to comply

with § 814.39. As a result, FDA estimates that the new total number of hours needed to comply with the information collection requirements in § 814.39 is 32,612 for a reduction of 3,451 hours.



FDA estimates the burden for this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
814.39	493	1	493	66.15	32,612

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: July 31, 1998

July 31, 1998

William K. Hubbard
Associate Commissioner for Policy Coordination

[FR Doc. 98–???? Filed ??–??–98; 8:45 am]

BILLING CODE 4160–01–F

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL